Portuguese Law (2004.08.19)

- Follows very closely the EU Clinical Trials Directive of 2001
- Separates the ethicial review from the scientifc assesment
- Includes the National Committee on Data Protection

Portuguese Law (2004.08.19)

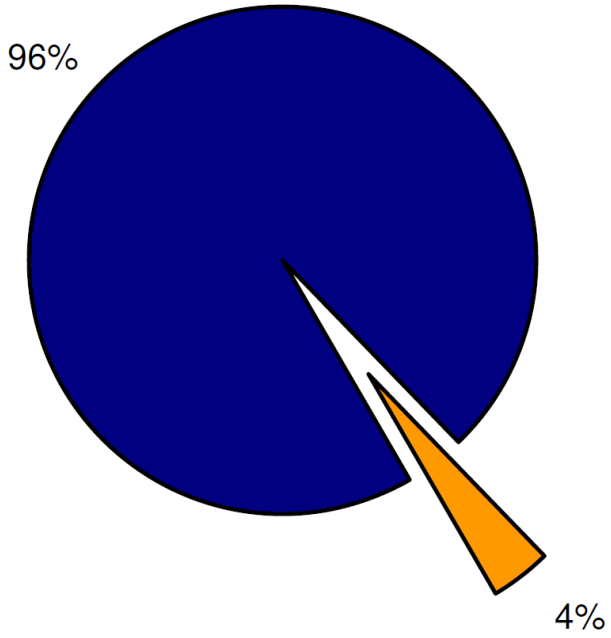
- Ethical review is done by a single, centralised Ethical Committee for Clinical Research (CEIC)
- Scientific assessment is done by the National Medicines Agency (INFARMED)
- **BUT**
- The ethical committee meets in the premises of the Medicines Agency
- Management support for the activity of the ethical commitee is provided by the staff of the Medicines Agency

Ethical Committee for Clinical Research (CEIC)

- Is nominated by the Minister for Health
- One president (currently a non-physician university teacher and researcher)
- One executive board (7 members)
- A total board of 35 members (mainly physicians, pharmacists, judges or lawyers, experts in bioethics, no formal patient representatives)

Comissão de Ética para a Investigação Clínica
National Ethics Committee for Clinical Investigation

Statistics for 2013 available on the Web site of CEIC



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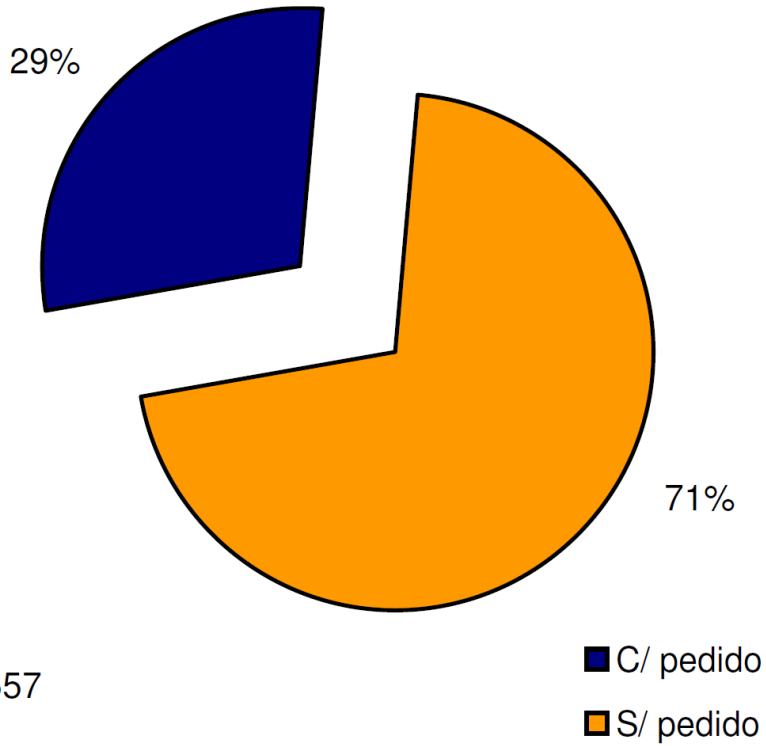

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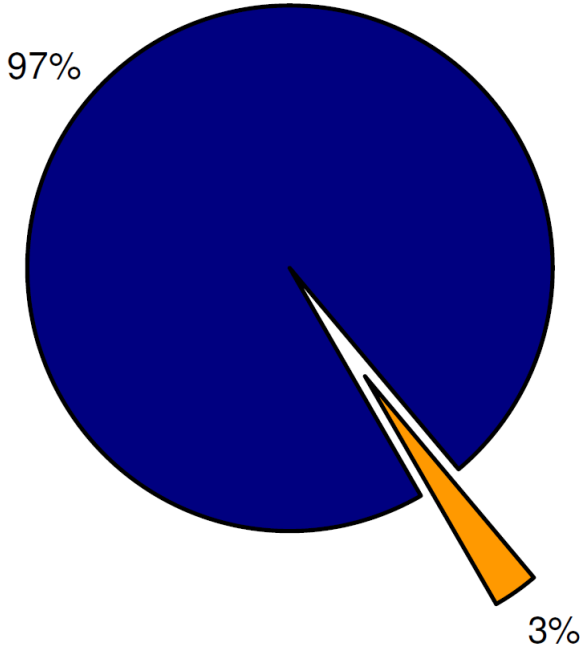
Further information required (blue) for new applications (left) or changes (right)

Comissão de Ética para a Investigação Clínica
National Ethics Committee for Clinical Investigation

Statistics for 2013 available on the Web site of CEIC



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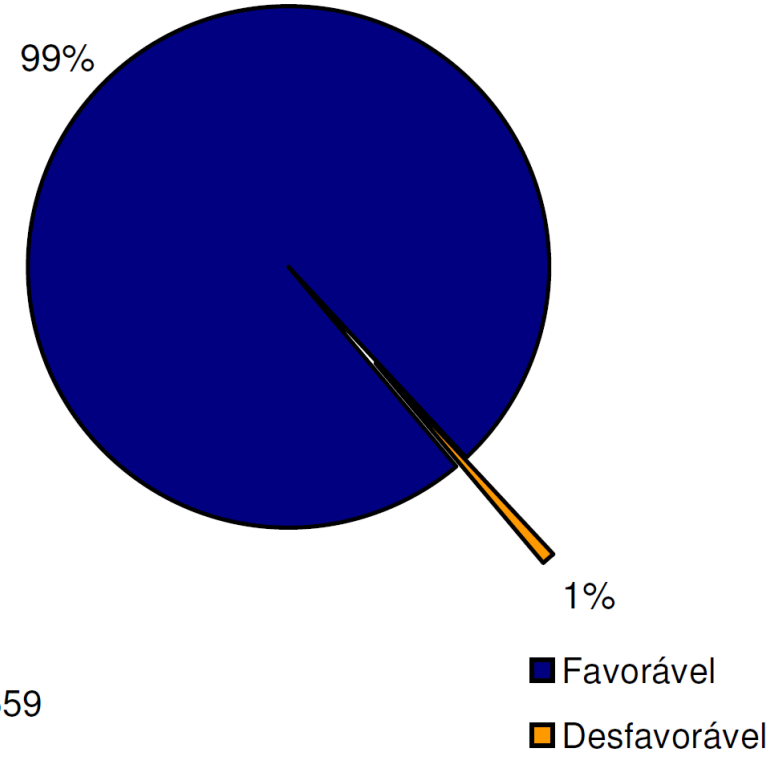

N= 559

Approvals (blue) for new applications (left) or changes (right)